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(71) Applicant: **ADVANCED CARDIOVASCULAR SYSTEMS, INC.**
Santa Clara California 95052 (US)

(72) Inventor: **Saunders, Richard J.**
Redwood City, California 94065 (US)

(74) Representative: **Mayes, Stuart David et al**
BOULT, WADE & TENNANT
27 Furnival Street
London, EC4A 1PQ (GB)

(54) Method and apparatus for direct laser cutting of metal stents

(57) An improved expandable stent (10) for implantation in a body lumen, such as an artery, and an improved method for making it from a single length of tubing. The stent (10) consists of a plurality of radially expandable cut cylindrical elements (12) generally aligned on a common axis and interconnected by one or more interconnective elements (13), the elements (12) having a rectangular cross-section from cut-to-cut. The individual radially expandable cylindrical elements (12) are disposed in an undulating pattern. The stent (10) is manufactured by direct laser cutting from a single metal tube using a finely focused laser beam passing through a coaxial gas jet structure to impinge on the working surface of the tube as the linear and rotary velocity of the tube is precisely controlled.

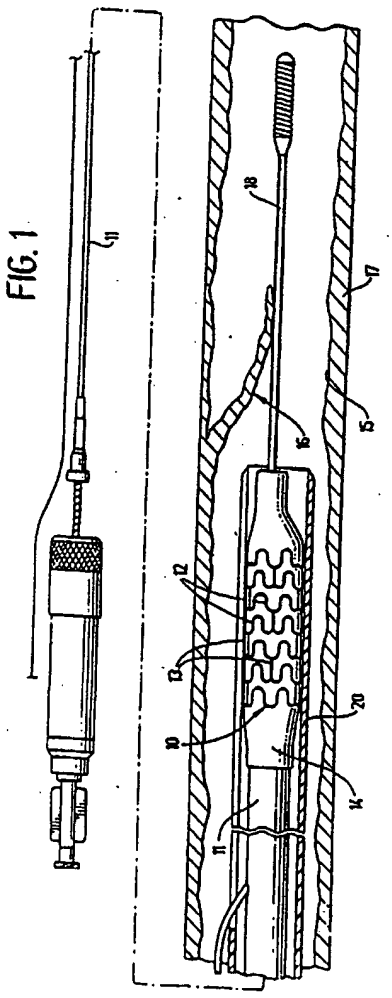

FIG. 1

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Description

BACKGROUND OF THE INVENTION

This invention relates generally to improvements in the manufacture of expandable metal stents and, more particularly, to new and improved methods and apparatus for direct laser cutting of metal stents and providing stents of enhanced structural quality.

Stents are expandable endoprosthesis devices which are adapted to be implanted into a body lumen of a patient, such as a blood vessel, to maintain the patency of the vessel. These devices typically are used in the treatment of atherosclerotic stenosis in blood vessels and the like.

In the medical arts, stents generally are tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. Stents particularly are suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway.

Various means have been provided to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the body lumen of a patient, inflating the balloon on the catheter to expand the stent into a permanently expanded condition and then deflating the balloon and removing the catheter.

One example of a particularly useful expandable stent is a stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially when in an expanded condition so as to maintain the patency of a body lumen such as an artery when implanted within the lumen. Such a desirable stent typically includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are precisely dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent when it is expanded. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced closely enough longitudinally so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so closely as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively resulting in a stent which is flexible along its length and about its longitudinal axis, but which is still very stiff in the radial direction in order to resist collapse.

The aforedescribed stents generally have a precisely laid out circumferential undulating pattern, e.g., serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one (2:1) or about one-half to one (0.5/1). A one to one (1:1) aspect ratio has been found to be particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall, which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern similar to changes in a waveform which result from decreasing the amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded so that the stent will remain in the expanded condition and, therefore, the structures must be sufficiently rigid when expanded to prevent collapse during deployment of the stent. Upon expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed into the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

The elongated elements which interconnect adjacent cylindrical elements should have a precisely defined transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed as a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. In this manner, there is no shortening of the stent upon expansion.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded, as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the more easily and the more safely it can be delivered to the implan-

tation site.

It will be apparent from the foregoing that conventional stents are very high-precision, relatively fragile devices and, ideally, the most desirable metal stents incorporate a fine precision structure cut from a very small diameter, thin-walled cylindrical tube. In this regard, it is extremely important to make precisely-dimensioned, smooth, narrow cuts in the stainless tubes in extremely fine geometries without damaging the narrow struts that make up the stent structure. While the various cutting processes, including chemical etching, heretofore have been used to form such expandable metal stents and have been adequate, improvements have been sought to provide stents of enhanced structural quality in terms of resolution, reliability and yield.

Accordingly, those concerned with the development, manufacture and use of metal stents long have recognized the need for the improved manufacturing processes for such stents.

SUMMARY OF THE INVENTION

Briefly, certain embodiments of the present invention provide a new and improved method and apparatus for direct laser cutting of metal stents enabling greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections that otherwise might hamper stent integrity and performance.

A first embodiment of the present invention provides an improved system for producing metal stents with a fine precision structure, cut from a small diameter, thin-walled, cylindrical tube. The tubes typically are made of stainless steel and are fixtured under a laser and positioned utilizing a computer numerical control (CNC) fixture to generate a very intricate and precise pattern. Due to the thin-wall and the small geometry of the stent pattern, it is necessary to have very precise control of the laser, its power level, the focus spot size, and the positioning of the laser cutting path.

In a presently preferred embodiment of the invention, in order to minimize the heat input, to avoid thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, a Q-switched Nd:YAG(neodymium: yttrium aluminum garnet) laser that is frequency doubled to produce a green beam at 532 nanometers is used Q-switching produces very short pulses (< 100 nanoseconds) of high peak powers (kilowatts), low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller than is a non-frequency doubled beam and, therefore, the power density is increased by a factor of four. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that comprise the stent structure.

In addition to the laser and the CNC positioning equipment, the optical delivery system used in the practice of the present invention includes a beam expander to increase the laser beam diameter; a circular polarizer to eliminate polarization effects in metal cutting; provisions for a spatial filter; a binocular viewing head and focusing lens; and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle is centered around the focused beam with approximately 0.25 millimeters (0.01 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 3.87 cm-Hg (20 lbs/in^2) and is directed at the tube with the focused laser beam exiting the tip of the nozzle. The oxygen reacts with the metal to assist in the cutting process very similar to what occurs with oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube inside diameter, a stainless steel mandrel is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This mandrel acts as a beam/debris block, protecting the far wall inside diameter.

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.013 millimeters (0.0005 inch) with the molten slag resolidifying along the cut. This traps the cut-out scrap of the pattern and which requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is desirable to soak the cut tube in a solution of hydrochloric acid (HCL) for a selected time and temperature. Before it is soaked, the tube is placed in a bath of alcohol and water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. After soaking, the tube then is ultrasonically cleaned in the heated HCL for a period of time dependent upon the wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. At completion of this process, the stent structures are rinsed in water. They are then ready for electropolishing.

Hence, the new and improved method and apparatus for direct laser cutting of metal stents, embodying the present invention, make accurate, reliable, high resolution, expandable stents with patterns having smooth, narrow cuts and very fine geometries.

The above and other objects and advantages of this invention will be apparent from the following more detailed description when taken in conjunction with the accompanying drawings of exemplary embodiments.

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery;

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall;

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter;

FIG. 4 is a perspective view of a stent embodying the invention in an unexpanded state, with one end of the stent being shown in an exploded view to illustrate the details thereof;

FIG. 5 is a plan view of a flattened section of a stent which illustrates the undulating pattern of the stent shown in FIG. 4;

FIG. 5a is a sectional view taken along the line 5a-5a in FIG. 5;

FIG. 6 is a schematic representation of equipment for selectively cutting the tubing in the manufacture of stents;

FIG. 7 is an elevational view of a system for cutting an appropriate pattern by laser in a metal tube to form a stent;

FIG. 8 is a plan view of the laser head and optical delivery subsystem for the laser cutting system shown in FIG. 7;

FIG. 9 is an elevational view of a coaxial gas jet, rotary collet, tube support and beam blocking apparatus for use in the system of FIG. 7;

FIG. 10 is a sectional view taken along the line 10-10 in FIG. 9;

FIG. 11 is an elevational and schematic drawing of laser beam diameter versus spot size and depth of focus; and

FIG. 12 is an elevational and schematic drawing of focal length versus spot size and depth of focus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and particularly to FIG. 1 thereof, there is shown a stent 10 which is mounted onto a delivery catheter 11. The stent 10 is a high-precision patterned tubular device. The stent 10 typically comprises a plurality of radially expanded cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG. 1 has a dissected lining 16 which has occluded a portion of the arterial passageway.

The typical delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as that manufactured under the tradename "SURLYN" by the Polymer Products Division of the E. I. Du Pont deNemours Company. Other polymers also may be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20, as described in copending application Serial No. 07/647,464 filed on April 25, 1990 and entitled STENT DELIVERY SYSTEM, may be provided to further insure that the stent stays in place on the expandable portion of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 20 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g., tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

The delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10

onto the exterior of the balloon. The catheter-stent assembly is introduced to the vasculature of the patient in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section having the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of the stent 10 which are pressed into the wall of the artery 15 eventually will be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Further, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15, as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially-expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 preferably are placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4, the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120° apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60° from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g., at the peaks of the undulations or along the sides of the undulations as shown in FIG. 5.

As best observed in FIGS. 4 and 5, cylindrical elements 12 are in the form of a serpentine pattern. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. The serpentine pattern is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

The afordescribed illustrative stent 10 and similar stent structures can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, such as stainless steel tubing, to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. In accordance with the invention, it is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser as illustrated schematically in FIG. 6.

The tubing may be made of suitable biocompatible material such as stainless steel. The stainless steel tube may be Alloy type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2; Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

Carbon (C)	0.03% max.
Manganese (Mn)	2.00% max.
Phosphorous (P)	0.025% max.
Sulphur (S)	0.010% max.
Silicon (Si)	0.75% max.
Chronium (Cr)	17.00 - 19.00%
Nickel (Ni)	13.00 - 15.50%
Molybdenum (Mo)	2.00 - 3.00%
Nitrogen (N)	0.10% max.
Copper (Cu)	0.50% max.
Iron (Fe)	Balance

The stent diameter is very small, so the tubing from which it is made necessarily must also have a small diameter.

Typically the stent has an outer diameter on the order of about 1.52 millimeters (0.06 inch) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 2.54 millimeters (0.1 inch) or more. The wall thickness of the tubing is about 0.076 millimeters (0.003 inch).

Referring to FIG. 6, the tubing 21 is put in a fixture having rotatable collets 22 of a machine-controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which also is machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent.

The process of cutting a pattern for the stent into the tubing is automated except for the loading and unloading of the length of tubing. Referring again to FIG. 6 loading may be accomplished for example, using a CNC-opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 25 to move the length of tubing axially relatively to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2 laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating.

Referring now to FIGS. 7-10 of the drawings, there is shown a process and apparatus, in accordance with the invention, for producing metal stents with a fine precision structure cut from a small diameter thin-walled cylindrical tube. Cutting a fine structure (0.09 millimeter (0.0035 inch) web width) requires minimal heat input and the ability to manipulate the tube with precision. It also is necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of 1.524 millimeters to 1.676 millimeters (0.060 inch to 0.066 inch) and a wall thickness of 0.051 millimeters to 0.102 millimeters (0.002 inch to 0.004 inch). These tubes are fixtured under a laser and positioned using a CNC to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern (0.09 millimeter (0.0035 inch) typical web width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris-free cut, a Q-switched Nd:YAG laser typically available from Quantronix of Hauppauge, New York is used, that is frequency-doubled to produce a green beam at 532 nanometers. Q-switching produces very short pulses (<100 nanoseconds) of high peak powers (kilowatts), low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller than a non-frequency doubled beam, therefore increasing the power density by a factor of 4 times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that make up the stent structure. Hence, the system described makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by the Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both circular and linear interpolation to be used in the programming. Because the finished structure of the stent is very small, a precision drive mechanism is required that supports and drives both ends of the tubular structure as it is cut. Since both ends are driven, they must be aligned and precisely synchronized, otherwise the stent structure would twist and distort as it is being cut. A suitable computer program for controlling the CNC equipment is enclosed herewith as Appendix A.

The optical system which expands the original laser beam, delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It also is necessary to block the beam as it cuts through the top surface of the tube and to prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.457 millimeter (0.018 inch) inner diameter (I.D.)) is centered around the focused beam with approximately 0.254 millimeter (0.010 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 3.87 cm-Hg (20 lbs/in^2) and is directed at the tube with the focused laser beam exiting the tip of the nozzle (0.457 millimeter (0.018 inch) diameter). The oxygen reacts with the metal to assist in the cutting process very similar to the reaction that takes place during oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the

tube inner diameter (I.D.) a stainless steel mandrel (approximately 0.864 millimeter (0.034 inch) diameter) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

Alternatively, this debris collection can accomplished by inserting a second tube, inside the stent tube which has an opening to trap the excess energy in the beam that is transmitted through the kerf as well as the debris that is ejected from the laser-cut kerf. A vacuum or positive pressure can be placed in this shielding tube to remove the collected of debris.

Another technique that could be used to remove the debris from the kerf and to cool the surrounding material would be to use the inner beam blocking tube as an internal gas jet. By sealing one end of the tube, making a small hole in the side, and placing it directly under the focused laser beam, gas pressure could be applied creating a small jet that would force the debris out of the laser-cut kerf from the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris then easily could be removed.

In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Compressed air is used in this application because it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gas such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there usually is a tail of molten material that collects along the exit side of the gas jet which must be removed mechanically or chemically after the cutting operation.

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.0127 millimeter (0.0005 inch)) with the molten slag resolidifying along the cut. This traps the cut-out scrap of the pattern which requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCL for approximately 8 minutes at a temperature of approximately 55° C. Before it is soaked, the tube is placed in a bath of alcohol and water solution and ultrasonically is cleaned for approximately 1 minute, to remove the loose debris left from the cutting operation. After soaking, the tube then is ultrasonically cleaned in the heated HCL for 1 to 4 minutes, depending upon the wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern, as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. At completion of this process, the stent structures are rinsed in water. They are now ready for electropolishing.

The stents preferably are electrochemically polished, in an acidic aqueous solution such as a solution marketed under the tradename ELECTRO-GLO #300 by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 43.3 to 57.2°C (110 to 135°F) and the current density is about 0.4 to about 1.5 amps/in.^{2}. Cathode to anode area should be at least about two to one. The stents further may be treated if desired, for example by applying a biocompatible coating.

Referring now more particularly to FIGS. 11 and 12, it will be apparent that both focused laser spot size and depth of focus can be controlled by selecting beam diameter (FIG. 11) and focal length for the focusing lens (FIG. 12). It will be apparent from FIGS. 11 and 12 that increasing laser beam diameter, or reducing lens focal length, reduces spot size at the expense of depth of field.

Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and similar processes which produce pattern edges that are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are square or rectangular rather than trapezoidal; see FIG. 5a. The resulting stent structure provides superior performance.

It will be apparent from the foregoing that the described system provides a new and improved method and apparatus for direct laser cutting of metal stents enabling greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections which might otherwise hamper stent integrity and performance. While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

APPENDIX A

```
G69 152C6048.QSY
G69 CUTS 1 STENT
G   UNEVEN U DES. W/END CONFIGS.
G69 0.0048 BAR WIDTH-.060 DIA.
G69 9/12/94
G69 PROGRAM 11 DISK 70
G69 CYCLE TIME = 20 MIN.20 SEC

V1=6    G69 LINEAR CUT
V2=30   G69 ROTARY+LIN. CUT
V3=25   G69 R+L FR CUT (FINGER ENDS)
V4=50   G69 ROTARY CUT
V5=500  G69 ROTARY INDEX
V6=10   G69 SHORT STRAIGHT CUT
V7=15   G69 LONG SLANT
V8=20
G66 Z55 1
G59 Z.006
G68 Z-1 (MIRROR IMAGE Z AXIS)
M108
G90 X0 Y0 Z0F300
M0

G69 PROGRAM BODY

G91X.15 F200
KN5000          G69 CALL .015" HOLES
F   000         G69 CALL CROSS HAIR

G90 Z-60 F300   G69 START PATTERN
KN1000          G69 CALL FIRST PATTERN
G90 Z-180 F300
KN1000
G90 Z-300 F300
KN1000
G91 X.042

N1234
G90 Z0 F300
KN2200 R5       G69 MAIN PATTERN
KN3300          G69 ADDITIONAL PATTERN
G90 Z-37.8 F300
G91 X.0512

KN3000          G69 CALLS END PATTERN
G90 Z-157.8 F300
KN3000
G90 Z-277.8 F300
KN3000
G90 X1.2888 F200
G91 M109
Z360 M108 FV4
```

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G90 X0 F200
G   M109
Z-.360 M108 FV4
G90 X0 Y2.5 F300
M0
M2

N2200            G69 MAIN PATTERN
G90 Z0 FV5
KN2000
G90 Z-120 FV5
KN2000
G90 Z-240 FV5
KN2000
G91 X.0492 F50
G90 Z-300 FV5
KN2000
G90 Z-180 FV5
KN2000
G90 Z-60 FV5
KN2000
G91 X.0492 F50
M6

N3300            G69 ADDITIONAL PATTERN
G90 Z0 FV5
G   300
G90 Z-120 FV5
KN2000
G90 Z-240 FV5
KN2000
M6

N4000            G69 CROSS HAIR SUB
G91 M109 FV1
X.01 M108
X-.005 Y.005
M109
Y-.01 M108
X.05 Y.005 F100
M6

N5000          G69 HOLES
M109
X.0075 F3
G3I-.0075 J0 M108
X-.0075 F200
G91 Z180 F300
M109
X.0075 F3
G3I-.0075J0M108
```

```
(-0075 Z-180 F500
(   F200
46

N1000   G69 FIRST PATTERN
391 M109
N1001 G9X.028937 Z0          FV1
N1002 X.000780 Z-0.802141    FV2
N1003 X.001255 Z-4.663876
N1004 X.001866 Z-4.209330
N1005 X.002307 Z-3.239121
N1006 X.002646 Z-2.005352
N1007 X.002782 Z-0.511842    FV6
N1008 X.019383 Z0.000000     FV1
N1009 X.001651 Z0.511842     FV3
N1010 X.001187 Z0.647442
N1011 X.002137 Z1.944237
N1012 X.002171 Z1.684496     FV6
N1013 X.002510 Z0.324676
N1014 X.002476 Z-1.166924
N1015 X.002137 Z-2.526744    FV2
N1016 X.001459 Z-3.628733
N1017 X.000814 Z-4.276175
N1018 X.000034 Z-2.916355
N1019 X-.000678 Z-3.304057
N1020 X-.000882 Z-1.749431
N1021 X-.002001 Z-1.359820   FV6
N1022 X-.001764 Z0.129870
N1023 X-.001866 Z1.166924
N1024 X-.001560 Z1.424755    FV3
N1025 X-.002001 Z0.972118
N1026 X-.001852 Z0.242552
N1027 X-.019467 Z0.000000    FV1
N1028 X-.002462 Z-0.630254   FV3
N1029 X-.002341 Z-1.684496

X-.011 Z3
X.011 Z-3

N1030 X-.002103 Z-2.979381   FV2
N1031 X-.001730 Z-3.951499
N1032 X-.001255 Z-4.535916
N1033 X-.000432 Z-4.919798
N1034 X.000509 Z-4.923617
N1035 X.001195 Z-4.06609
N1036 X-.001195 Z-4.06609
N1037 X-.000509 Z-4.923617
N1038 X.000432 Z-4.919798
N1039 X.001255 Z-4.535916
N1040 X.001730 Z-3.951499
N1041 X.002103 Z-2.979381
```

```
X-.011 Z-3
X  .1 Z3

N1042 X.002341 Z-1.684496  FV3
N1043 X.002462 Z-0.630254
N1044 X.019467 Z0          FV1
N1045 X.001852 Z0.242552   FV3
N1046 X.002001 Z0.972118
N1047 X.001560 Z1.424755
N1048 X.001866 Z1.166924   FV6
N1049 X.001764 Z0.129870
N1050 X.002001 Z-1.35982
N1051 X.000882 Z-1.749431  FV2
N1052 X.000678 Z-3.304057
N1053 X-.000034 Z-2.916355
N1054 X-.000814 Z-4.276175
N1055 X-.001459 Z-3.628733
N1056 X-.002137 Z-2.526744
N1057 X-.002476 Z-1.166924 FV6
N1058 X-.002510 Z0.324676
N1059 X-.002171 Z1.684496
N1060 X-.002137 Z1.944237  FV3
N1061 X-.001187 Z0.647442
N1062 X-.001651 Z0.511842
N1063 X-.019383 Z0          FV1
N1064 X-.002782 Z-0.511842 FV6
N1065 X-.002646 Z-2.005352 FV2
N1066 X-.002307 Z-3.239121
N1067 X-.001866 Z-4.20933
N1068 X-.001255 Z-4.663876
N1069 X-.000780 Z-0.802141
N1070 X-.028937 Z0          FV1

G69 RETURN TRIP

N1071 X-.004643 Z0.324676  FV6
N1072 X-.002980 Z1.058062
N1073 X-.002772 Z2.513375  FV2
N1074 X-.002425 Z3.307876
N1075 X-.001940 Z4.763189
N1076 X-.000693 Z11.37703
N1077 X.002841 Z9.921719
N1078 X.005405 Z2.513375   FV6
N1079 X.005682 Z-2.513375
N1080 X.023615 Z-21.95383  FV2
N1081 X.006375 Z14.74984
N1082 X-.005026 Z13.11118
N1083 X-.001951 Z15.82891
N1084 X.001951 Z15.82891
N1085 X.005026 Z13.11118
N1086 X-.006375 Z14.74984
N1087 X-.023615 Z-21.95383
```

```
N1088 X-.005682 Z-2.513375 FV6
N  19 X-.005405 Z2.513375
N1090 X-.002841 Z9.921719  FV2
N1091 X.000693 Z11.37703
N1092 X.001940 Z4.763189
N1093 X.002425 Z3.307876
N1094 X.002772 Z2.513375
N1095 X.002980 Z1.058062   FV6
N1096 X.004643 Z0.324676 G0 M108
M6

N2000   G69 MAIN PATTERN
G91
M109
N1 G9X.036364 Z0           FV1
N2  X.000780 Z-0.802141    FV2
N3  X.001255 Z-4.663876
N4  X.001866 Z-4.209330

X-.0034 Z-3
X.0034 Z3

N5  X.002307 Z-3.239121
N6  X.002646 Z-2.005352
N7  X.002782 Z-0.511842    FV6
N8  X.019383 Z0            FV1
N9  X.001651 Z0.511842     FV6
N10 X.001187 Z0.647442
N11 X.002137 Z1.944237
N12 X.002171 Z1.684496
N13 X.002510 Z0.324676
N14 X.002476 Z-1.166924
N15 X.002137 Z-2.526744    FV2
N16 X.001459 Z-3.628733
N17 X.000814 Z-4.276175
N18 X.000034 Z-2.916355
N19 X-.000678 Z-3.304057
N20 X-.000882 Z-1.749431
N21 X-.002001 Z-1.359820   FV6
N22 X-.001764 Z0.129870
N23 X-.001866 Z1.166924
N24 X-.001560 Z1.424755
N25 X-.002001 Z0.972118
N26 X-.001852 Z0.242552

N27 X-.019467 Z0.000000    FV1
N28 X-.002462 Z-0.630254   FV6
N29 X-.002341 Z-1.684496   FV2
N30 X-.002103 Z-2.979381
N31 X-.001730 Z-3.951499

X-.004Z3
```

```
X-.004Z-3

N32 X-.001255 Z-4.535916
N33 X-.000432 Z-4.919798
N34 X.000509 Z-4.923617
N35 X.001195 Z-4.06609
N36 X-.001195 Z-4.06609
N37 X-.000509 Z-4.923617
N38 X.000432 Z-4.919798
N39 X.001255 Z-4.535916

X-.004 Z-3
X.004 Z3

N40 X.001730 Z-3.951499
N41 X.002103 Z-2.979381
N42 X.002341 Z-1.684496
N43 X.002462 Z-0.630254    FV6
N44 X.019467 Z0            FV1
N45 X.001852 Z0.242552     FV6
N46 X.002001 Z0.972118
N47 X.001560 Z1.424755
N48 X.001866 Z1.166924
N49 X.001764 Z0.129870
N50 X.002001 Z-1.35982
N51 X.000882 Z-1.749431    FV2
N52 X.000678 Z-3.304057
N53 X-.000034 Z-2.916355
N54 X-.000814 Z-4.276175
N55 X-.001459 Z-3.628733
N56 X-.002137 Z-2.526744
N57 X-.002476 Z-1.166924   FV6
N58 X-.002510 Z0.324676
N59 X-.002171 Z1.684496
N60 X-.002137 Z1.944237
N61 X-.001187 Z0.647442
N62 X-.001651 Z0.511842
N63 X-.019383 Z0           FV1
N64 X-.002782 Z-0.511842   FV6
N65 X-.002646 Z-2.005352   FV2
N66 X-.002307 Z-3.239121

X-.0034 Z3
X.0034 Z-3

N67 X-.001866 Z-4.20933
N68 X-.001255 Z-4.663876
N69 X-.000780 Z-0.902141
N70 X-.036364 Z0           FV1

369  RETURN TRIP
```

```
N[illegible] X-.000508 Z0.475555   FV3
N[illegible] X-.000882 Z1.294885
N[illegible] X-.000333 Z2.196338
N74 X.000084 Z1.75898
N75 X.000469 Z1.694045
N76 X.000703 Z1.822006
N77 X.001038 Z1.566085
N78 X.001424 Z0.926282
N79 X.020432 Z0            FV1
N80 X.001965 Z-0.765854    FV6
N81 X.002137 Z-1.879302
N82 X.002510 Z-1.101989
N83 X.002442 Z-0.194806
N84 X.002374 Z0.907183
N85 X.002239 Z2.202068     FV2
N86 X.002001 Z3.239121
N87 X.001560 Z4.728812
N88 X.000746 Z5.246384
N89 X-.000170 Z5.635995
N90 X-.000916 Z5.443099
N91 X-.001391 Z4.665786
N92 X-.001823 Z3.884654
N93 X-.002375 Z3.109251
N94 X-.002714 Z2.267003
N95 X-.002680 Z0.907183    FV6
N96 X-.002884 Z-0.064935
N[illegible] X-.002714 Z-1.165014
N[illegible] X-.002273 Z-2.007262  FV3
N99 X-.001798 Z-1.489690
N100 X-.001081 Z-0.529031
N101 X-.018795 Z0.000000   FV1
N102 X-.001766 Z0.655082   FV2
N103 X-.001391 Z1.489690
N104 X-.001187 Z2.396873
N105 X-.000950 Z3.498862
N106 X-.000101 Z2.188699
N107 X.000101 Z2.188699
N108 X.000950 Z3.498862
N109 X.001187 Z2.396873
N110 X.001391 Z1.489690
N111 X.001766 Z0.655082
N112 X.018795 Z0.000000   FV1
N113 X.001081 Z-0.529031   FV3
N114 X.001798 Z-1.489690
N115 X.002273 Z-2.007262
N116 X.002714 Z-1.165014   FV6
N117 X.002884 Z-0.064935
N118 X.002680 Z0.907183
N119 X.002714 Z2.267003    FV2
N120 X.002375 Z3.109251
N121 X.001823 Z3.884654
N122 X.001391 Z4.665786
```

```
N123 X.000916 Z5.443099
N124 X.000170 Z5.635995
N125 X-.000746 Z5.246384
N126 X-.001560 Z4.728812
N127 X-.002001 Z3.239121
N128 X-.002239 Z2.202068
N129 X-.002374 Z0.907183    FV6
N130 X-.002442 Z-0.194806
N131 X-.002510 Z-1.101989
N132 X-.002137 Z-1.879302
N133 X-.001965 Z-0.765854
N134 X-.020432 Z0.000000    FV1
N135 X-.001424 Z0.926282    FV3
N136 X-.001038 Z1.566085
N137 X-.000703 Z1.822006
N138 X-.000469 Z1.694045
N139 X-.000084 Z1.75898
N140 X.000333 Z2.196338
N141 X.000882 Z1.294885
N142 X.000508 Z0.475555 M108 G0
M6


N3000  G69 END PATTERN
G91M109
N2001 G9X.020432 Z 0        FV1
N2002 X.001965 Z-.7659      FV8
N2003 X.002137 Z-1.8793
N2004 X.002510 Z-1.1020     FV6
N2005 X.002442 Z-.1948
N2006 X.002374 Z.9072
N2007 X.002239 Z 2.2021     FV8
N2008 X.002001 Z 3.2391
N2009 X.001560 Z 4.7288
N2010 X.035000 Z 0          FV1
N2011 X.005068 Z-1.6024     FV3
N2012 X.002576 Z-4.1024
N2013 X.001288 Z-6.5623
N2014 X-.000572 Z-5.4698
N2015 X-.003148 Z-8.4760
N2016 X-.005438 Z-6.0161
N2017 X-.008014 Z-2.1868
N2018 X-.019320 Z 10.1184 FV7
N2019 X-.003148 Z-8.7510

X-.008 Z-4  ——— Z-7
X.008 Z4    ——— Z 7

N2020 X.005152  Z-13.1246 FV2
N2021 X0        Z-17.5287
N2022 X-.005152 Z-13.1246 FV3
```

```
X  008 Z4                    FV7
)  )8 Z-4

N2023 X.003148 Z-8.7510
N2024 X.019320 Z 10.1184
N2025 X.008014 Z-2.1868
N2026 X.005438 Z-6.0161
N2027 X.003148 Z-8.4760
N2028 X.000572 Z-5.4698
N2029 X-.001288 Z-6.5623
N2030 X-.002576 Z-4.1024
N2031 X-.005068 Z-1.6024
N2032 X-.034424 Z 0          FV1
N2033 X-.000916 Z 5.4431     FV2
N2034 X-.001391 Z 4.6658
N2035 X-.001823 Z 3.8847
N2036 X-.002375 Z 3.1093
N2037 X-.002714 Z 2.2670
N2038 X-.002680 Z.9072       FV6
N2039 X-.002884 Z-.0649
N2040 X-.002714 Z-1.1650
N2041 X-.002273 Z-2.0073     FV2
N2042 X-.001798 Z-1.4897
N2043 X-.001081 Z-.5290
N2044 X-.018795 Z0           FV1
N2045 X-.001766 Z .6551      FV3
N 46 X-.001391 Z 1.4897
1  47 X-.001187 Z 2.3969
N2048 X-.000950 Z 3.4989
N2049 X-.000101 Z 2.1887
N2050 X.000101 Z 2.1887
N2051 X.000950 Z 3.4989
N2052 X.001187 Z 2.3969
N2053 X.001391 Z 1.4897
N2054 X.001766 Z.6551
N2055 X.018795 Z 0           FV1
N2056 X.001081 Z-.5290       FV2
N2057 X.001798 Z-1.4897
N2058 X.002273 Z-2.0073
N2059 X.002714 Z-1.1650      FV6
N2060 X.002884 Z-.0649
N2061 X.002680 Z.9072
N2062 X.002714 Z 2.2670      FV2
N2063 X.002375 Z 3.1093
N2064 X.001823 Z 3.8847
N2065 X.001391 Z 4.6658
N2066 X.000916 Z 5.4431
N2067 X.000170 Z 5.6360
N2068 X-.000746 Z 5.2464
N2069 X-.001560 Z 4.7288
N2070 X-.002001 Z 3.2391
N2071 X-.002239 Z 2.2021
```

```
N2072 X-.002374 Z.9072     FV6
N2073 X-.002442 Z-.1948
N2074 X-.002510 Z-1.1020
N2075 X-.002137 Z-1.8793   FV2
N2076 X-.001965 Z-.7659
N2077 X-.020432 Z0         FV1
N2078 X-.001424 Z.9263
N2079 X-.001038 Z 1.5661 FV3
N2080 X-.000703 Z 1.8220
N2081 X-.000469 Z 1.6940
N2082 X-.000084 Z 1.7590
N2083 X.000333  Z 2.1963
N2084 X.000869  Z 2.7120
N2085 X.000239  Z 2.2804
N2086 X0        Z 4.3086
N2087 X-.000239 Z 2.2804
N2088 X-.000869 Z 2.7120
N2089 X-.000333 Z 2.1963
N2090 X.000084 Z 1.7590
N2091 X.000469 Z 1.6940
N2092 X.000703 Z 1.8220
N2093 X.001038 Z 1.5661
N2094 X.001424 Z.9263G0
M108
M6

N0001
(    F300
X0 Y2.5 Z0
M0
```

Claims

1. A longitudinal flexible stent for implanting in a body lumen, comprising:

   a plurality of cut cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis, each cylindrical element having a rectangular cross-section from one cut edge to another; and
   a plurality of connecting elements for interconnecting said cut cylindrical elements, said connecting elements configured to interconnect said cylindrical elements that are adjacent to each other.

2. The stent of claim 1, wherein said plurality of cut cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

3. The stent of claim 2, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, some of said U-shaped, Y-shaped, and W-shaped members being interconnected.

4. The stent of claim 1, wherein at least some of said plurality of cut cylindrical elements tip radially outwardly to form outwardly projecting edges upon radial expansion of said stent.

5. The stent of claim 1, wherein said cut cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

6. The stent of claim 1, wherein said stent is formed of stainless steel.

7. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

8. A method of making an expandable metal stent, comprising the steps of:

supporting a metal tube for controlled linear and rotary motion;
impinging a finely focused laser beam upon the working surface of said metal tube; and
providing a protective mandrel within said tube to protect the tube wall opposite the tube wall being cut from being ablated by said laser beam,
whereby a precise pattern is cut into said tube to form said stent.

9. A method as set forth in claim 8, wherein said metal tube is stainless steel.

10. A method as set forth in claim 8, wherein said protective mandrel is stainless steel.

11. A method as set forth in claim 8, wherein said laser beam is circularly polarized.

12. A method as set forth in claim 11, wherein said circular polarization is accomplished by a quarter wave plate.

13. A method as set forth in claim 8, wherein said laser beam is spatially filtered.

14. A method as set forth in claim 8, wherein the size of the focused laser beam spot and depth of field is controlled by selecting beam diameter.

15. A method as set forth in claim 8, wherein the size of the focused laser beam spot and depth of field is controlled by selecting focal length of the beam focusing lens.

16. A method as set forth in claim 8, wherein said laser beam passes through a coaxial gas jet adjacent said tube.

17. A method as set forth in claim 16 wherein the gas is oxygen.

18. A method as set forth in claim 8 and further including the steps of:
ultrasonically cleaning said stent after it is formed.

19. A method as set forth in either of claims 1 or 18, and further including the step of electropolishing said stent after it is formed.

FIG. 1

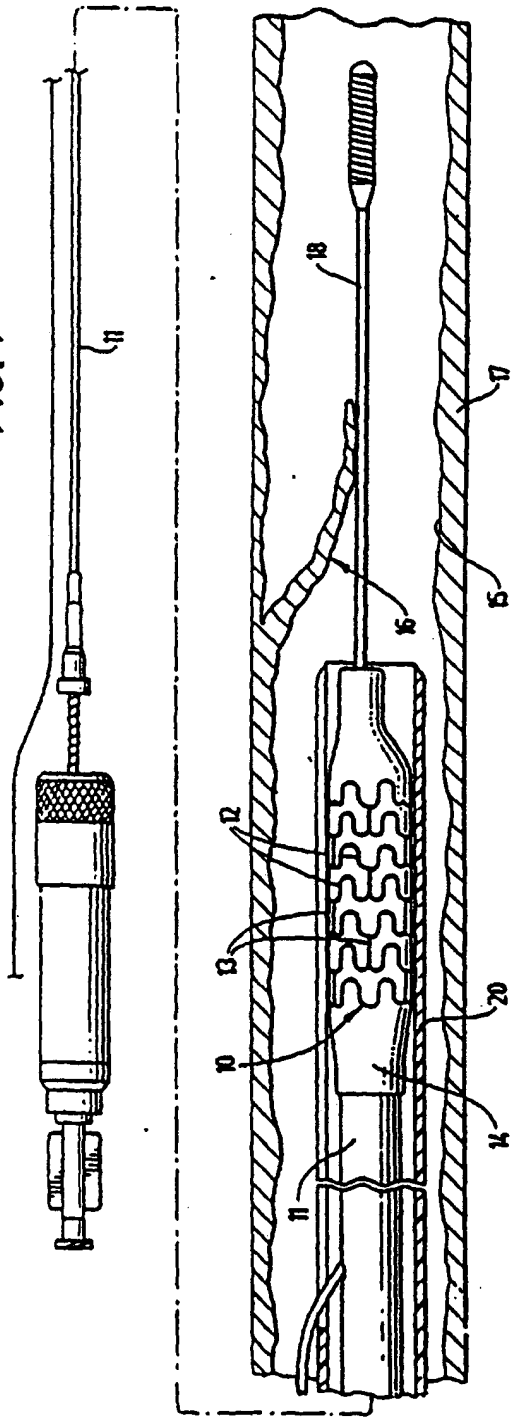


FIG. 3

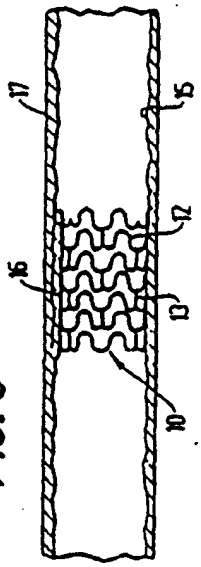


FIG. 2

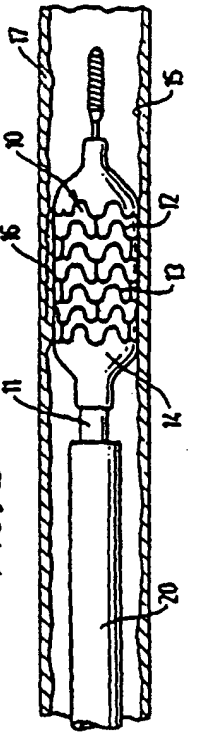


FIG. 4

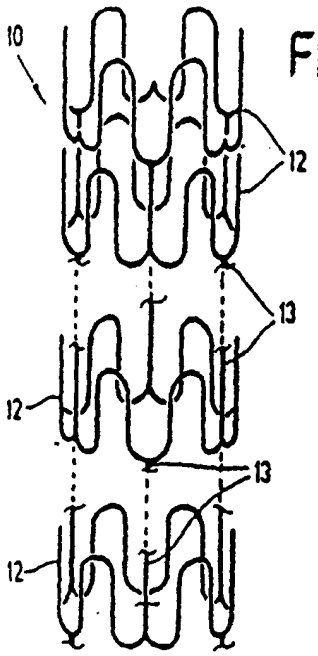


FIG. 6

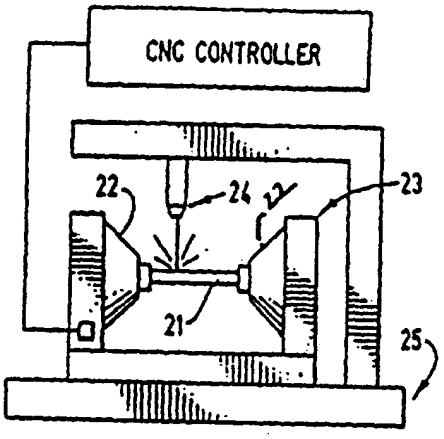


FIG. 5

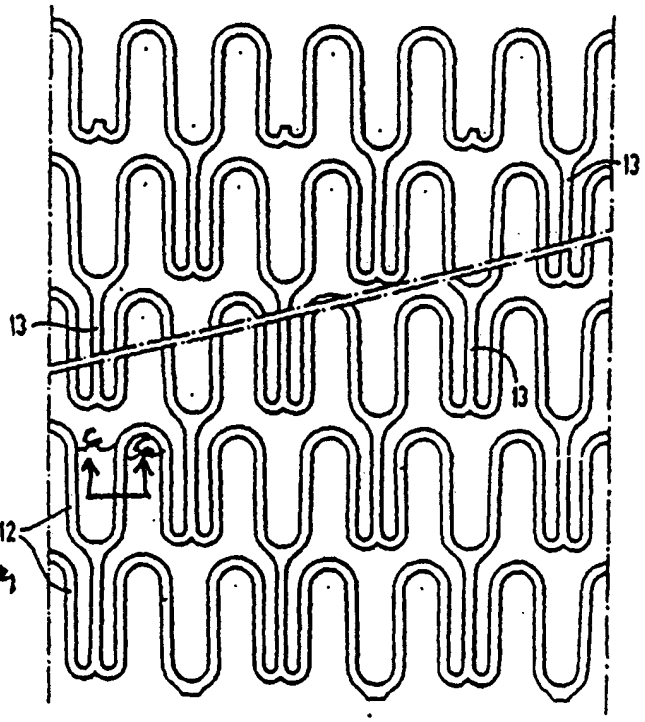
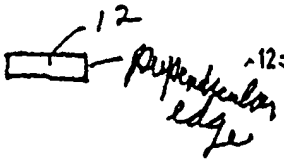


FIG. 5a



LASER HEAD, OPTICAL DELIVERY SYSTEM, X,Y,Ø STAGES

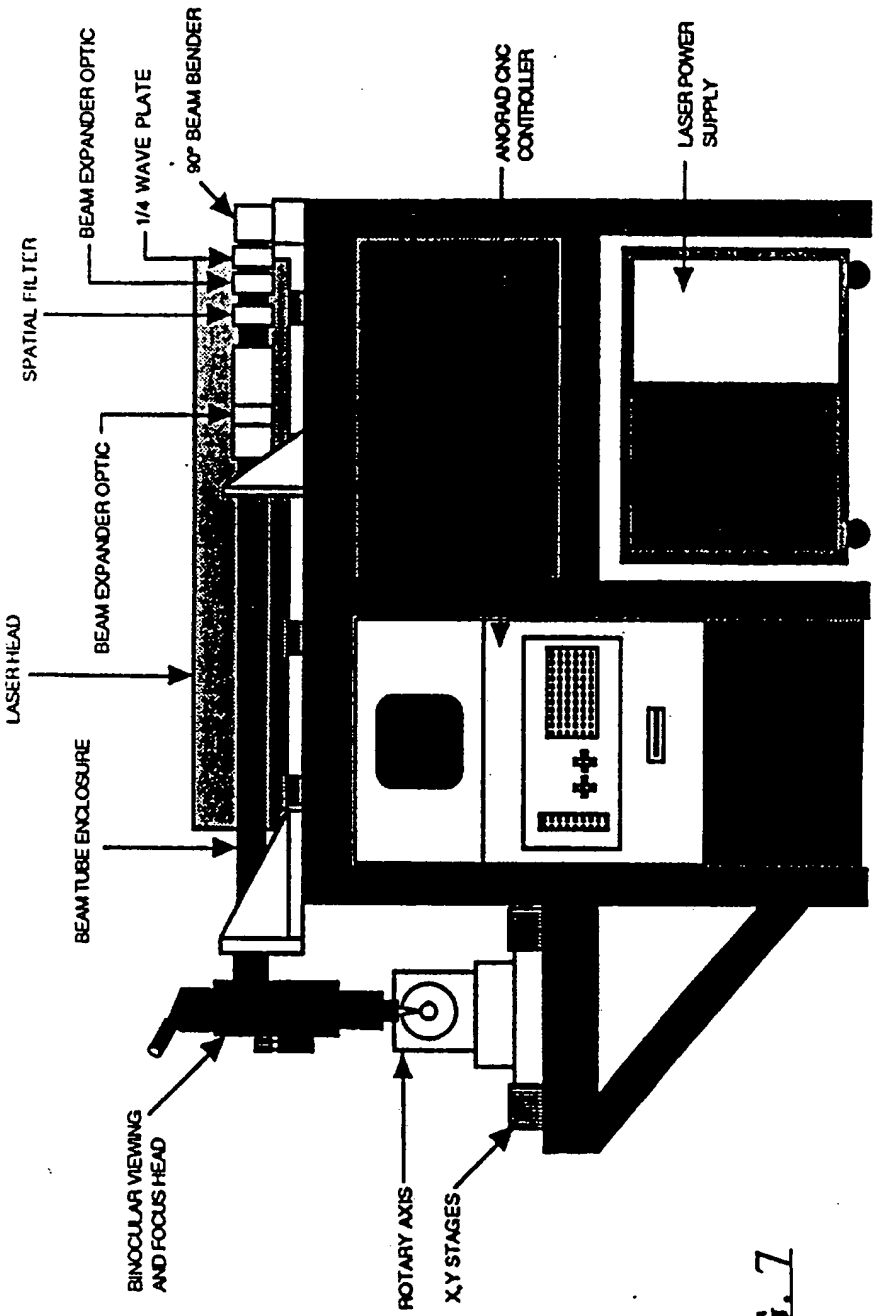
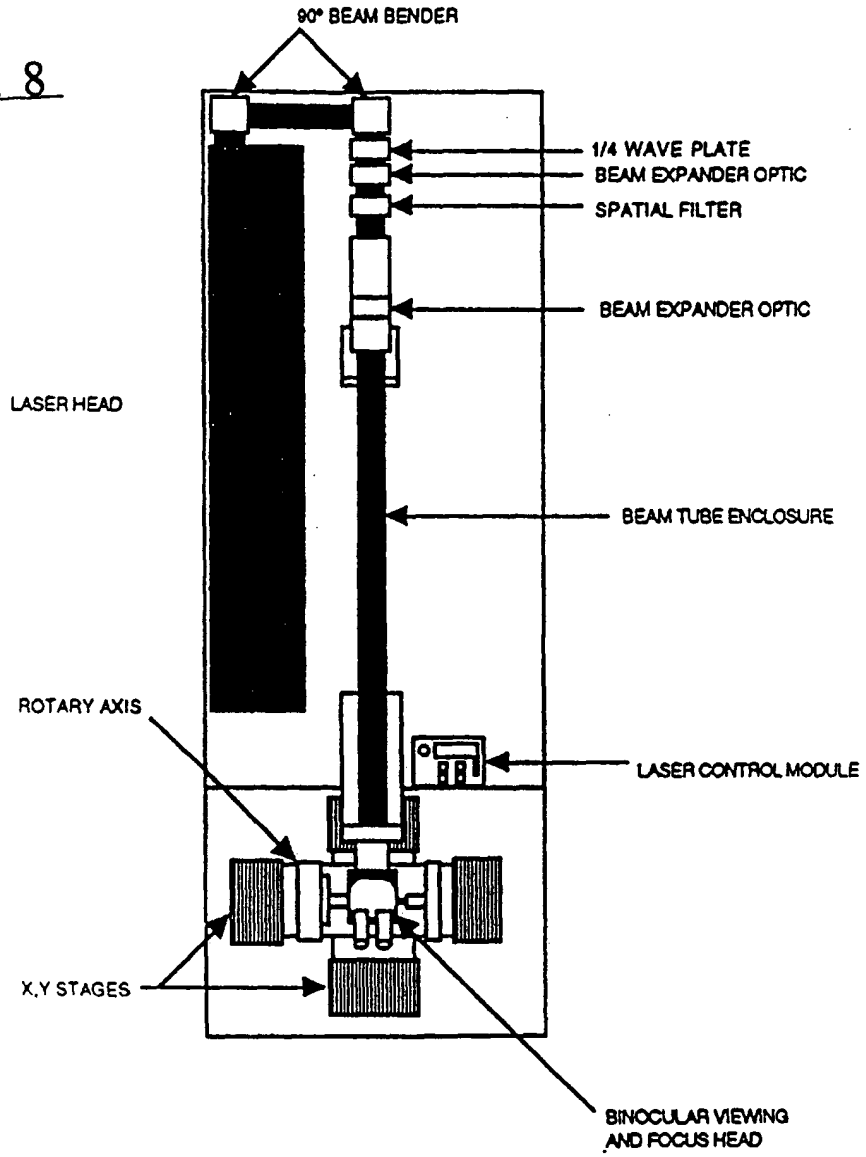


FIG. 7

FIG. 8


LASER HEAD, OPTICAL DELIVERY SYSTEM, X,Y,Ø STAGES
90° BEAM BENDER
1/4 WAVE PLATE
BEAM EXPANDER OPTIC
SPATIAL FILTER
BEAM EXPANDER OPTIC
LASER HEAD
BEAM TUBE ENCLOSURE
ROTARY AXIS
LASER CONTROL MODULE
X,Y STAGES
BINOCULAR VIEWING AND FOCUS HEAD

COAXIAL GAS JET - ROTARY COLLET AND
TUBE SUPPORT - TUBE BEAM BLOCK

FIG. 9

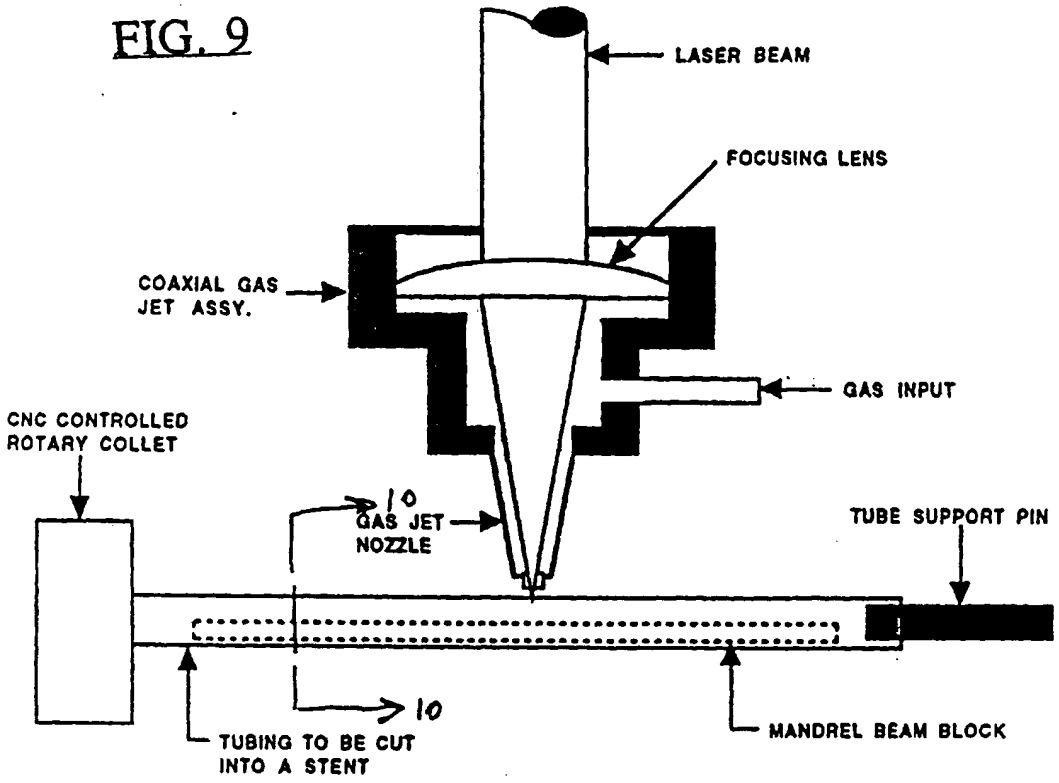
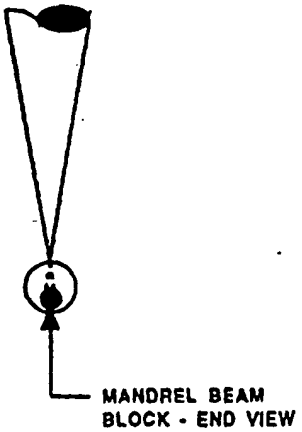
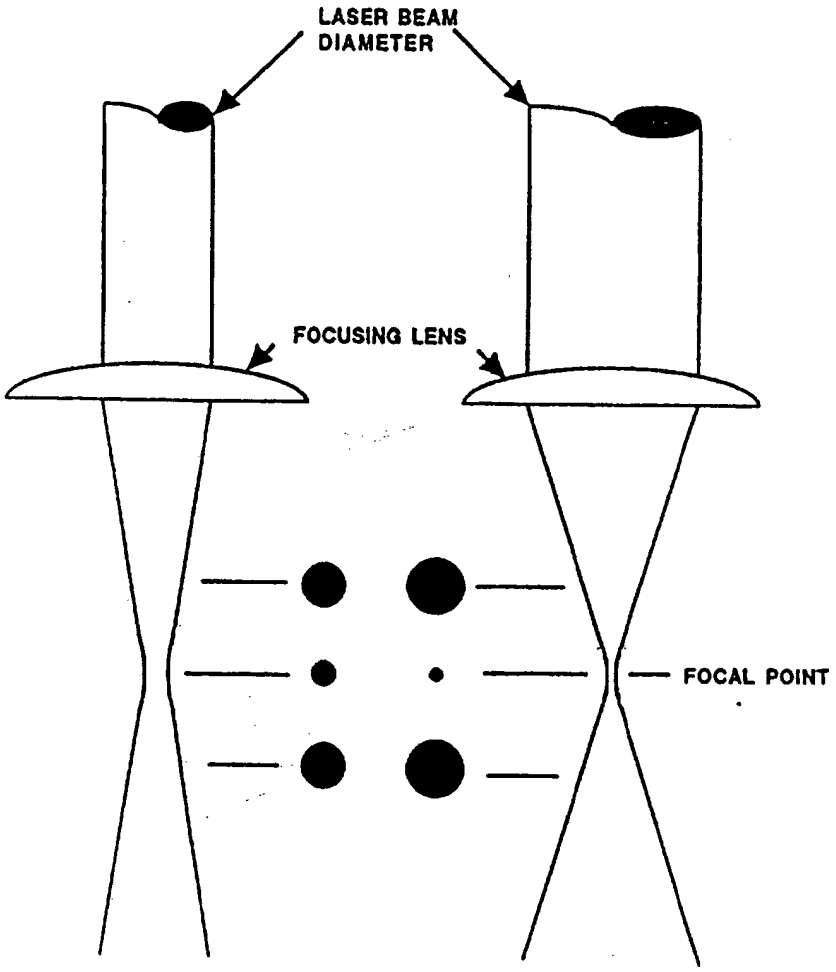


FIG. 10



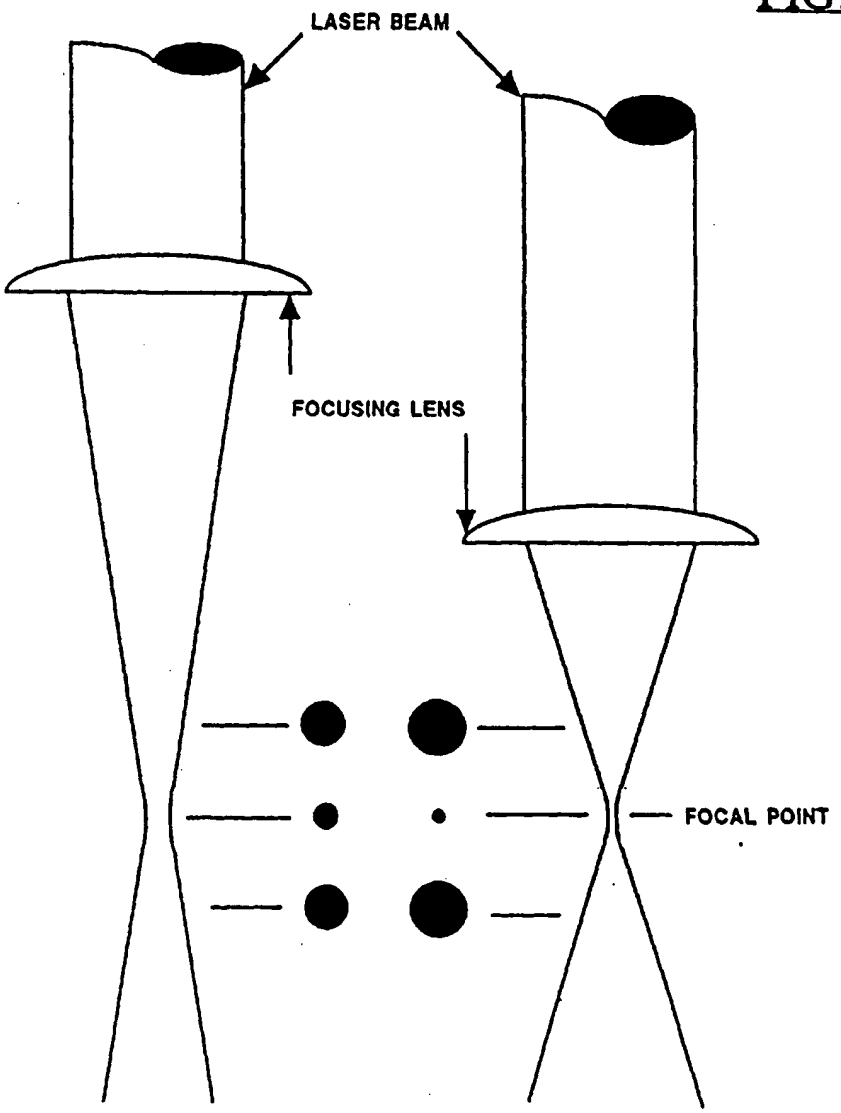
BEAM DIAMETER VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 11



FOCAL LENGTH VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 12



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 8554

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 540 290 (ADVANCED CARDEOVASCULAR SYSTEM) 5 May 1993 * the whole document *	1-10	A61F2/06 B23K26/08
A		16,17	
Y	EP-A-0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 * column 7, line 28 - column 8, line 48; figures *	1-7	
Y	EP-A-0 562 150 (SCHABLONENTECHNIK KUFSTEIN GMBH) 29 September 1993 * column 10, line 40 - column 11, line 2; figures *	8-10	
P,X	EP-A-0 662 307 (ADVANCED CARDEOVASCULAR SYSTEM) 12 July 1995 * column 6, line 45 - line 51; claims; figures *	1-8	
A	EP-A-0 221 570 (PALMAZ JULIO C) 13 May 1987 * column 7, line 52 - column 8, line 24; figures *	1-3,5-7	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61F B23K
A	EP-A-0 372 789 (GEN ELECTRIC) 13 June 1990 * column 6, line 13 - column 7, line 5; figures *	8,9,11, 16	
A	GB-A-2 070 490 (FERRANTI LTD) 9 September 1981 * abstract * * page 1, line 13 - line 15 *	8,11,12, 16	
A	US-A-4 963 022 (SOMMARGREN GARY E) 16 October 1990 * abstract; figures *	8,13	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	12 November 1996	Neumann, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filling more than ten claims

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the claims fees have been paid within the prescibed time limit. The present European search report has been drawn up for the first ten claims and those claims for which fees have been

namely claims:

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of the unity of the invention and relates to several inventions or groups of inventions, namely:

see sheet B

☒ All further search fees haven been paid within the fixed time limit. The present European search report has been drawn up for all claims

☐ Only part of the further claims fees have been paid within the prescibed time limit. The present European search report has been drawn up for for those parts of the European patent application which relate to the inventions in respects of which search fees have been paid,

namely claims:

☐ None of the further claims fees have been paid within the prescibed time limit. The present European search report has been drawn up for for those parts of the European patent application which relate to the invention first mentioned in the claims,

namely claims:

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 8554

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US-A-4 387 952 (SLUSHER ROBERT B) 14 June 1983 * abstract; figures *	8,14	
A	EP-A-0 624 421 (RUSSIAN TECHNOLOGY GROUP) 17 November 1994 * abstract *	8,15	
P,A	EP-A-0 679 373 (ADVANCED CARDEOVASCULAR SYSTEM) 2 November 1995 * the whole document *	1-8,16	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	12 November 1996	Neumann, E

CATEGORY OF CITED DOCUMENTS

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L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

EP 95 30 8554

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims 1-7 : A flexible stent made of cylindrical elements having a rectangular cross-section and connecting members.

2. Claims 8-19 : Method of making a stent including the step of cutting a pattern with a laser beam.

(19) Europäisches Patentamt
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(54) Method for direct laser cutting of metal stents

Verfahren zum Direktlaserstrahlschneiden eines metallischen Stents

Procédé pour coupage au laser direct d'un dilatateur en métal

(84) Designated Contracting States:
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(73) Proprietor:
ADVANCED CARDIOVASCULAR SYSTEMS, INC.
Santa Clara California 95052 (US)

(72) Inventor: **Saunders, Richard J.**
Redwood City, California 94065 (US)

(74) Representative:
McLeish, Nicholas Allstair Maxwell et al
Boult Wade Tennant
27 Furnival Street
London EC4A 1PQ (GB)

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EP-A- 0 364 787
EP-A- 0 372 789
EP-A- 0 540 290
EP-A- 0 562 150
EP-A- 0 624 421
EP-A- 0 662 307
EP-A- 0 679 373
GB-A- 2 070 490
US-A- 4 387 952
US-A- 4 963 022

EP 0 714 641 B1

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Description

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to improvements in the manufacture of expandable metal stents and, more particularly, to new and improved methods for direct laser cutting of metal stents and providing stents of enhanced structural quality.

[0002] Stents are expandable endoprosthesis devices which are adapted to be implanted into a body lumen of a patient, such as a blood vessel, to maintain the patency of the vessel. These devices typically are used in the treatment of atherosclerotic stenosis in blood vessels and the like.

[0003] In the medical arts, stents generally are tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. Stents particularly are suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway.

[0004] Various means have been provided to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the body lumen of a patient, inflating the balloon on the catheter to expand the stent into a permanently expanded condition and then deflating the balloon and removing the catheter.

[0005] One example of a particularly useful expandable stent is a stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially when in an expanded condition so as to maintain the patency of a body lumen such as an artery when implanted within the lumen. Such a desirable stent typically includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are precisely dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and are preferably positioned to prevent warping of the stent when it is expanded. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced closely enough longitudinally so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so closely as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively resulting in a stent which is flexible along its length and about its longitudinal axis, but which is still very stiff in the radial direction in order to resist collapse.

[0006] The aforedescribed stents generally have a precisely laid out circumferential undulating pattern, e.g., serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one (2:1) or about one-half to one (0.5/1). A one to one (1:1) aspect ratio has been found to be particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall, which can improve the healing and repair of a damaged arterial lining.

[0007] The radial expansion of the expandable cylinder deforms the undulating pattern similar to changes in a waveform which result from decreasing the amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded so that the stent will remain in the expanded condition and, therefore, the structures must be sufficiently rigid when expanded to prevent collapse during deployment of the stent. Upon expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed into the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

[0008] The elongated elements which interconnect adjacent cylindrical elements should have a precisely defined transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed as a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. In this manner, there is no shortening of the stent upon expansion.

[0009] The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded, as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the more easily and the

more safely it can be delivered to the implantation site.

[0010] It will be apparent from the foregoing that conventional stents are very high-precision, relatively fragile devices and, ideally, the most desirable metal stents incorporate a fine precision structure cut from a very small diameter, thin-walled cylindrical tube. In this regard, it is extremely important to make precisely-dimensioned, smooth, narrow cuts in the stainless tubes in extremely fine geometries without damaging the narrow struts that make up the stent structure. For example, EP-A-0,540,290 describes a stent made by coating a length of tubing with an etchant-resistive material and then selectively removing portions of the coating to expose the portions of the tubing to be removed. This is done by machine-controlled activation and relative positioning of a laser in conjunction with the coated tubing. The stent is then formed by removing the exposed portions of the tubing by an etching process.

[0011] While the various cutting processes, including chemical etching, heretofore have been used to form such expandable metal stents and have been adequate, improvements have been sought to provide stents of enhanced structural quality in terms of resolution, reliability and yield.

[0012] Accordingly, those concerned with the development, manufacture and use of metal stents long have recognized the need for the improved manufacturing processes for such stents.

SUMMARY OF THE INVENTION

[0013] Briefly, certain embodiments of the present invention provide a new and improved method for direct laser cutting of metal stents enabling greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections that otherwise might hamper stent integrity and performance.

[0014] According to the present invention there is provided a method of making an expandable metal stent, comprising the steps of: supporting a metal tube for controlled linear and rotary motion; and impinging a finely focused laser beam upon the working surface of said metal tube, characterised in that the method further comprises the step of providing a protective mandrel within said tube, the mandrel being sized so as to be able to roll on an inner surface of the metal tube thereby protecting the tube wall opposite the tube wall being cut from being ablated by said laser beam, whereby a precise pattern is cut into said tube to form said stent.

[0015] The tubes typically are made of stainless steel and are fixtured under a laser and positioned utilizing a Computer numerical control (CNC) fixture to generate a very intricate and precise pattern. Due to the thin-wall and the small geometry of the stent pattern, it is necessary to have very precise control of the laser, its power level, the focus spot size, and the positioning of the laser cutting path.

[0016] In a presently preferred embodiment of the invention, in order to minimize the heat input, to avoid thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, a Q-switched Nd:YAG(neodymium: yttrium aluminum garnet) laser is used that is frequency doubled to produce a green beam at 532 nanometers. Q-switching produces very short pulses (<100 nanoseconds) of high peak powers (kilowatts), with low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot Size that is 2 times smaller than a non-frequency doubled beam and, as a result, the power density is increased by a factor of four. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that comprise the stent structure.

[0017] In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter; a circular polarizer to eliminate polarization effects in metal cutting; provisions for a spatial filter; a binocular viewing head and focusing lens; and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle is centered around the focused beam with approximately 0.25 millimeters (0.01 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 137.9 kPa (3.87 cm-Hg or 20 lbs/in^2) and is directed at the tube with the focused laser beam exiting the tip of the nozzle. The oxygen reacts with the metal to assist in the cutting process in a very similar way to what occurs with oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube inside diameter, a stainless steel mandrel is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This mandrel acts as a beam/debris block, protecting the far wall inside diameter.

[0018] The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.013 millimeters (0.0005 inch) with the molten slag resolidifying along the cut. This traps the cut-out scrap of the pattern and requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is desirable to soak the cut tube in a solution of hydrochloric acid (HCL) for a selected time and temperature. Before it is soaked, the tube is placed in a bath of alcohol and water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. After soaking, the tube then is ultrasonically cleaned in the heated HCL for a period of time dependent upon the

wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. On completion of this process, the stent structures are rinsed in water. They are then ready for electropolishing.

[0019] Hence, the new and improved method for direct laser cutting of metal stents, which embodies the present invention, results in accurate, reliable, high resolution, expandable stents with patterns having smooth, narrow cuts and very fine geometries.

[0020] The above and other objects and advantages of this invention will be apparent from the following more detailed description when taken in conjunction with the accompanying drawings of exemplary embodiments.

DESCRIPTION OF THE DRAWINGS

[0021]

FIGURE 1 is an elevational view, partially in section, of a stent mounted on a delivery catheter and disposed within a damaged artery;

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall;

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter;

FIG. 4 is a perspective view of a stent in an unexpanded state, with one end of the stent being shown in an exploded view to illustrate the details thereof;

FIG. 5 is a plan view of a flattened section of a stent which illustrates the undulating pattern of the stent shown in FIG. 4;

FIG. 5a is a sectional view taken along the line 5a-5a in FIG. 5;

FIG. 6 is a schematic representation of equipment for selectively cutting the tubing in the manufacture of stents;

FIG. 7 is an elevational view of a system for cutting an appropriate pattern by laser in a metal tube to form a stent;

FIG. 8 is a plan view of the laser head and optical delivery subsystem for the laser cutting system shown in FIG. 7;

FIG. 9 is an elevational view of a coaxial gas jet, rotary collet, tube support and beam blocking apparatus for use in the system of FIG. 7;

FIG. 10 is a sectional view taken along the line 10-10 in FIG. 9;

FIG. 11 is an elevational and schematic drawing of laser beam diameter versus spot size and depth of focus; and

FIG. 12 is an elevational and schematic drawing of focal length versus spot size and depth of focus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0022] Referring now to the drawings, and particularly to FIG. 1 thereof, there is shown a stent 10 which is mounted onto a delivery catheter 11. The stent 10 is a high-precision patterned tubular device. The stent 10 typically comprises a plurality of radially expanded cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG. 1 has a dissected lining 16 which has occluded a portion of the arterial passageway.

[0023] The typical delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as that manufactured under the tradename "SURLYN" by the Polymer Products Division of the E. I. Du Pont deNemours Company. Other polymers also may be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20, as described in US Patent No. 5,507,768 and entitled STENT DELIVERY SYSTEM, may be provided to further insure that the stent stays in place on the expandable portion of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 20 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon.

[0024] Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g., tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

[0025] The delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon. The catheter-stent assembly is introduced to the vasculature of the patient in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section having the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

[0026] The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of the stent 10 which are pressed into the wall of the artery 15 eventually will be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Further, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15, as illustrated in FIGS. 2 and 3.

[0027] FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially-expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 preferably are placed to achieve maximum flexibility for a stent. In the example shown in FIG. 4, the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120° apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60° from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion.

[0028] The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g., at the peaks of the undulations or along the sides of the undulations as shown in FIG. 5.

[0029] As best observed in FIGS. 4 and 5, cylindrical elements 12 are in the form of a serpentine pattern. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. The serpentine pattern is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

[0030] The afordescribed illustrative stent 10 and similar stent structures can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, such as stainless steel tubing, to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. In accordance with the invention, it is preferred to cut the tubing in the desired pattern by means of a laser as illustrated schematically in FIG. 6.

[0031] The tubing may be made of suitable biocompatible material such as stainless steel. The stainless steel tube may be Alloy type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2; Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

Carbon (C)	0.03% max.
Manganese (Mn)	2.00% max.
Phosphorous (P)	0.025% max.
Sulphur (S)	0.010% max.
Silicon (Si)	0.75% max.
Chromium (Cr)	17.00 - 19.00%
Nickel (Ni)	13.00 - 15.50%
Molybdenum (Mo)	2.00 - 3.00%
Nitrogen (N)	0.10% max.
Copper (Cu)	0.50% max.
Iron (Fe)	Balance

The stent diameter is very small, so the tubing from which it is made necessarily must also have a small diameter. Typically the stent has an outer diameter on the order of about 1.52 millimeters (0.06 inch) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 2.54 millimeters (0.1 inch) or more. The wall thickness of the tubing is about 0.076 millimeters (0.003 inch).

[0032] Referring to FIG. 6, the tubing 21 is put in a fixture having rotatable collets 22 of a machine-controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which also is machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent.

[0033] The process of cutting a pattern for the stent into the tubing is automated except for the loading and unloading of the length of tubing. Referring again to FIG. 6 loading may be accomplished for example, using a CNC-opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 25 to move the length of tubing axially relatively to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2 laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating.

[0034] Referring now to FIGS. 7-10 of the drawings, there is shown a process in accordance with the invention, for producing metal stents with a fine precision structure cut from a small diameter thin-walled cylindrical tube. Cutting a fine structure (0.09 millimeter (0.0035 inch) web width) requires minimal heat input and the ability to manipulate the tube with precision. It also is necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of 1.524 millimeters to 1.676 millimeters (0.060 inch to 0.066 inch) and a wall thickness of 0.051 millimeters to 0.102 millimeters (0.002 inch to 0.004 inch). These tubes are fixtured under a laser and positioned using a CNC to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern (0.09 millimeter (0.0035 inch) typical web width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

[0035] In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris-free cut, a Q-switched Nd:YAG laser typically available from Quantronix of Hauppauge, New York is used, that is frequency-doubled to produce a green beam at 532 nanometers. Q-switching produces very short pulses (<100 nanoseconds) of high peak powers (kilowatts), with low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller than a non-frequency doubled beam, thereby increasing the power density by a factor of 4 times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that make up the stent structure. Hence, the described system makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

[0036] The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by the Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both circular and linear interpolation to be used in the programming. Because the finished structure of the stent is very small, a precision drive mechanism is required that supports and drives both ends of the tubular structure as it is cut. Since both ends are driven, they must be aligned and precisely synchronized, otherwise the stent structure would twist and distort as it is being cut.

[0037] The optical system which expands the original laser beam, delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It also is necessary to block the beam as it cuts through the top surface of the tube and to prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

[0038] In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.457 millimeter (0.018 inch) inner diameter (I.D.)) is centered around the focused beam with approximately 0.254 millimeter (0.010 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 137.9 kPa (3.87 cm-Hg or 20 lbs/in^2) and is directed at the tube with the focused laser beam exiting the tip of the nozzle (0.457 millimeter (0.018 inch) diameter). The oxygen reacts with the metal to assist in the cutting process in a very similar way to the reaction that takes place during oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube inner diameter (I.D.) a stainless steel man-

drel (approximately 0.864 millimeter (0.034 inch) diameter) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

[0039] Another technique that could be used to remove the debris from the kerf and to cool the surrounding material would be to use an inner beam blocking tube as an internal gas jet. By sealing one end of the tube, making a small hole in the side, and placing it directly under the focused laser beam, gas pressure could be applied creating a small jet that would force the debris out of the laser-cut kerf from the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris then easily could be removed.

[0040] In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Compressed air is used in this application because it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gas such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there usually is a tail of molten material that collects along the exit side of the gas jet which must be removed mechanically or chemically after the cutting operation.

[0041] The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.0127 millimeter (0.0005 inch)) with the molten slag resolidifying along the cut. This traps the cut-out scrap of the pattern which requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a Solution of HCL for approximately 8 minutes at a temperature of approximately 55° C. Before it is soaked, the tube is placed in a bath of alcohol and water solution and is ultrasonically cleaned for approximately 1 minute, to remove the loose debris left from the cutting operation. After soaking, the tube is ultrasonically cleaned in the heated HCL for 1 to 4 minutes, depending upon the wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern, as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. On completion of this process, the stent structures are rinsed in water. They are now ready for electropolishing.

[0042] The stents preferably are electrochemically polished, in an acidic aqueous solution such as a solution marketed under the tradename ELECTRO-GLO #300 by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 43.3 to 57.2°C (110 to 135°F) and the current density is about 0.062 to about 0.233 amps/cm^2 (about 0.4 to about 1.5 amps/in.^{2}). Cathode to anode area should be at least about two to one. The stents further may be treated if desired, for example by applying a biocompatible coating.

[0043] Referring now more particularly to FIGS. 11 and 12, it will be apparent that both the focused laser spot size and the depth of focus can be controlled by selecting the beam diameter (FIG.11) and the focal length for the focusing lens (FIG. 12). It will be apparent from FIGS. 11 and 12 that increasing the laser beam diameter, or reducing the lens focal length, reduces the spot size at the expense of the depth of field.

[0044] Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and similar processes which produce pattern edges that are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are square or rectangular rather than trapezoidal; see FIG. 5a. The resulting stent structure provides superior performance.

[0045] It will be apparent from the foregoing that the described method for direct laser cutting of metal stents enables greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections which might otherwise hamper stent integrity and performance. While the invention has been illustrated and described herein in terms of making an intravascular stent, it will be apparent to those skilled in the art that the method can be used in other instances such as to make- prostatic urethras in cases of prostate hyperplasia.

[0046] It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

Claims

1. A method of making an expandable metal stent (10), comprising the steps of:

   supporting a metal tube (21) for controlled linear and rotary motion; and
   impinging a finely focused laser beam upon the working surface of said metal tube (21), characterised in that the method further comprises the step of
   providing a protective mandrel within said tube (21), the mandrel being sized so as to be able to roll on an inner surface of the metal tube (21) thereby protecting the tube wall opposite the tube wall being cut from being ablated by said

laser beam,

whereby a precise pattern 15 cut into said tube (21) to form said stent (10) .

2. A method as set forth in claim 1, wherein said metal tube (21) is stainless steel.

3. A method as set forth in claim 1, wherein said protective mandrel is stainless steel.

4. A method as set forth in claim 1, wherein said laser beam is circularly polarized.

5. A method as set forth in claim 4, wherein said circular polarization is accomplished by a quarter wave plate.

6. A method as set forth in claim 1, wherein said laser beam is spatially filtered.

7. A method as set forth in claim 1, wherein the size of the focused laser beam spot and depth of field is controlled by selecting beam diameter.

8. A method as set forth in claim 1, wherein the size of the focused laser beam spot and depth of field is controlled by selecting focal length of the beam focusing lens.

9. A method as set forth in claim 1, wherein said laser beam passes through a coaxial gas jet adjacent said tube (21).

10. A method as set forth in claim 9 wherein the gas is oxygen.

11. A method as set forth in claim 1 and further including the step of ultrasonically cleaning said stent (10) after it is formed.

12. A method as set forth in either of claims 1 or 11, and further including the step of electropolishing said stent (10) after it is formed.

Patentansprüche

1. Verfahren zum Herstellen eines expandierbaren Metall-Stents (10), umfassend die Schritte:

Halten eines Metallrohrs (21) für eine gesteuerte Linear- und Drehbewegung; und

Auftreffenlassen eines fein fokussierten Laserstrahls auf die Arbeitsfläche des Metallrohrs (21),
dadurch gekennzeichnet, daß das Verfahren ferner den Schritt des Vorsehens eines Schutzdorns in dem Rohr (21) umfaßt, wobei der Dorn derart bemessen ist, daß er auf einer Innenfläche des Metallrohrs (21) rollen kann, wodurch die Rohrwand, die derjenigen Rohrwand gegenüberliegt, die geschnitten wird, davor geschützt wird, durch den Laserstrahl abgetragen zu werden, wodurch ein präzises Muster in das Rohr (21) geschnitten wird, um den Stent (10) zu bilden.

2. Verfahren nach Anspruch 1, wobei das Metallrohr (21) aus rostfreiem Stahl ist.

3. Verfahren nach Anspruch 1, wobei der Schutzdorn aus rostfreiem Stahl ist.

4. Verfahren nach Anspruch 1, wobei der Laserstrahl zirkular polarisiert ist.

5. Verfahren nach Anspruch 4, wobei die zirkulare Polarisation durch ein Viertelwellenlängeplättchen erreicht wird.

6. Verfahren nach Anspruch 1, wobei der Laserstrahl raumgefiltert wird.

7. Verfahren nach Anspruch 1, wobei die Größe des fokussierten Laserstrahlspots und die Schärfentiefe durch Wählen des Strahldurchmessers gesteuert wird.

8. Verfahren nach Anspruch 1, wobei die Größe des fokussierten Laserstrahlspots und die Schärfentiefe durch Wählen der Brennweite der Strahlfokussierlinse gesteuert wird.

9. Verfahren nach Anspruch 1, wobei der Laserstrahl benachbart dem Rohr (21) durch einen koaxialen Gasstrahl läuft.

10. Verfahren nach Anspruch 9, wobei das Gas Sauerstoff ist.

11. Verfahren nach Anspruch 1 und ferner umfassend den Schritt des Ultraschallreinigens des Stents (10) nach seiner Bildung.

12. Verfahren nach Anspruch 1 oder 11 und ferner umfassend den Schritt des Elektropolierens des Stents (10) nach seiner Bildung.

Revendications

1. Procédé de fabrication d'un dilatateur métallique expansible (10), comprenant les étapes consistant :

à supporter un tube métallique (21) pour un déplacement linéaire et rotatif commandé ; et
à effectuer l'impact d'un faisceau laser focalisé

de manière fine sur la surface de travail dudit tube métallique (21), caractérisé en ce que le procédé comprend de plus l'étape consistant :

à prévoir un mandrin protecteur à l'intérieur dudit tube (21), le mandrin étant dimensionné de façon à être susceptible de rouler sur une surface intérieure du tube métallique (21) protégeant, de ce fait, la paroi du tube opposée à la paroi du tube en train d'être découpée contre toute découpe par ledit faisceau laser,
de sorte qu'un motif précis est découpé dans ledit tube (21) pour former ledit dilatateur (10).

2. Procédé selon la revendication 1, dans lequel ledit tube métallique (21) est en acier inoxydable.

3. Procédé selon la revendication 1, dans lequel ledit mandrin protecteur est en acier inoxydable.

4. Procédé selon la revendication 1, dans lequel ledit faisceau laser est polarisé de façon circulaire.

5. Procédé selon la revendication 4, dans lequel ladite polarisation circulaire est effectuée par une plaque quart d'onde.

6. Procédé selon la revendication 1, dans lequel ledit faisceau laser est filtré de façon spatiale.

7. Procédé selon la revendication 1, dans lequel la taille du point de faisceau laser focalisé et la profondeur de champ sont commandées en sélectionnant le diamètre du faisceau.

8. Procédé selon la revendication 1, dans lequel la taille du point de faisceau laser focalisé et la profondeur de champ sont commandées en sélectionnant la longueur focale de la lentille de focalisation de faisceau.

9. Procédé selon la revendication 1, dans lequel ledit faisceau laser passe à travers un jet de gaz coaxial adjacent audit tube (21).

10. Procédé selon la revendication 9, dans lequel le gaz est de l'oxygène.

11. Procédé selon la revendication 1 et comprenant de plus l'étape de nettoyage par ultrasons dudit dilatateur (10) après sa formation.

12. Procédé selon la revendication 1 ou 11, et comprenant de plus l'étape de polissage électrolytique dudit dilatateur (10) après sa formation.

FIG. 1

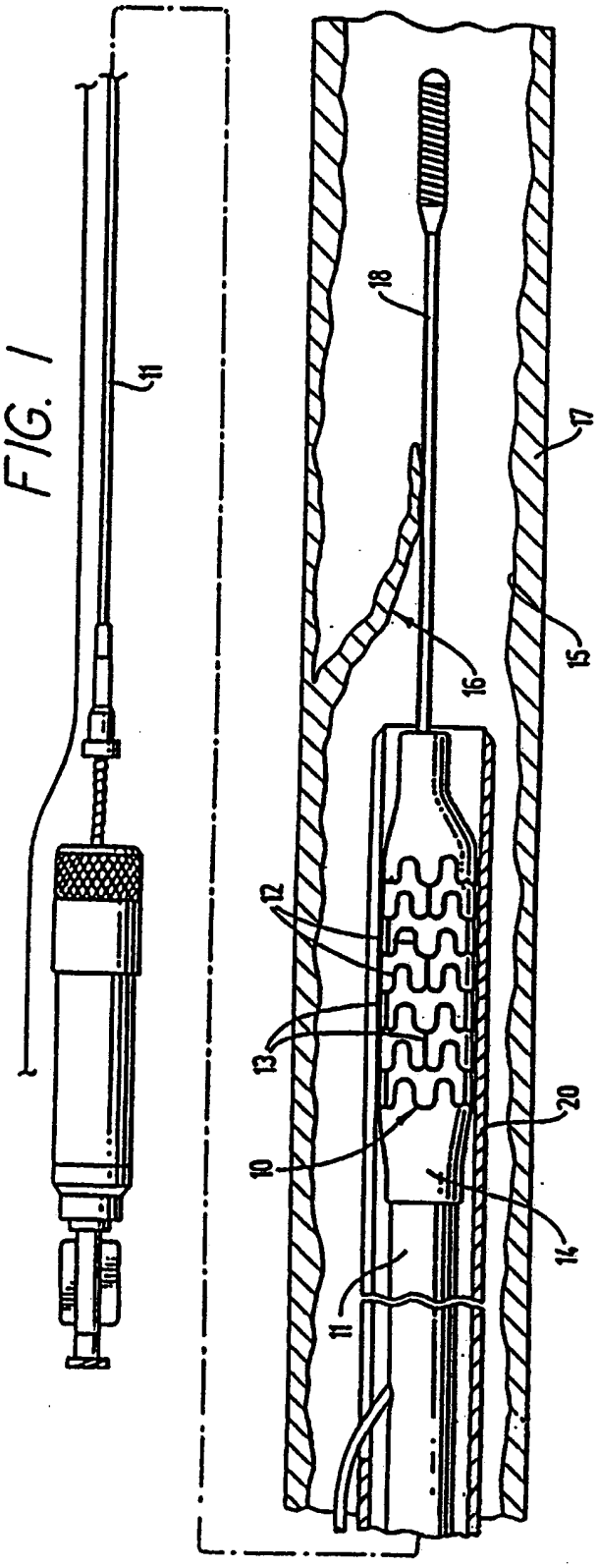


FIG. 3

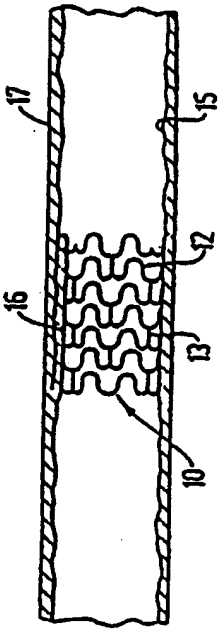


FIG. 2

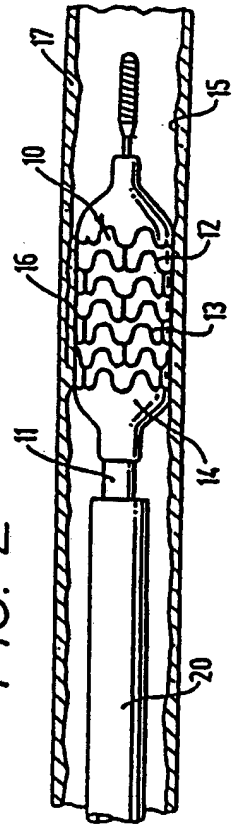


FIG. 4

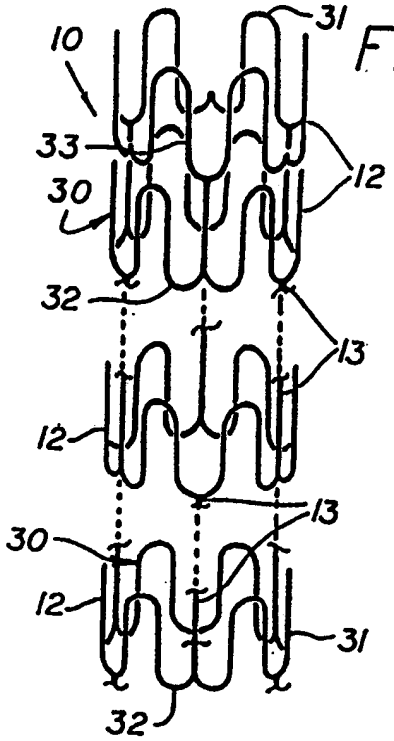


FIG. 6

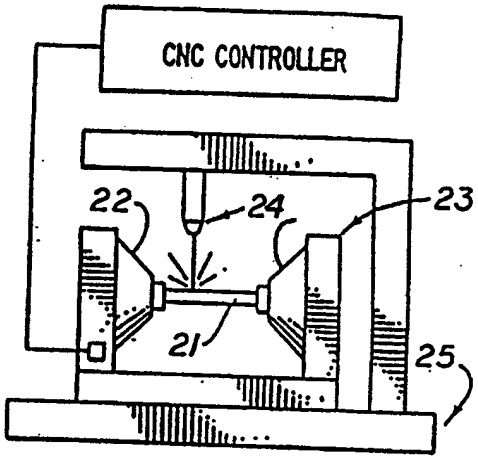


FIG. 5

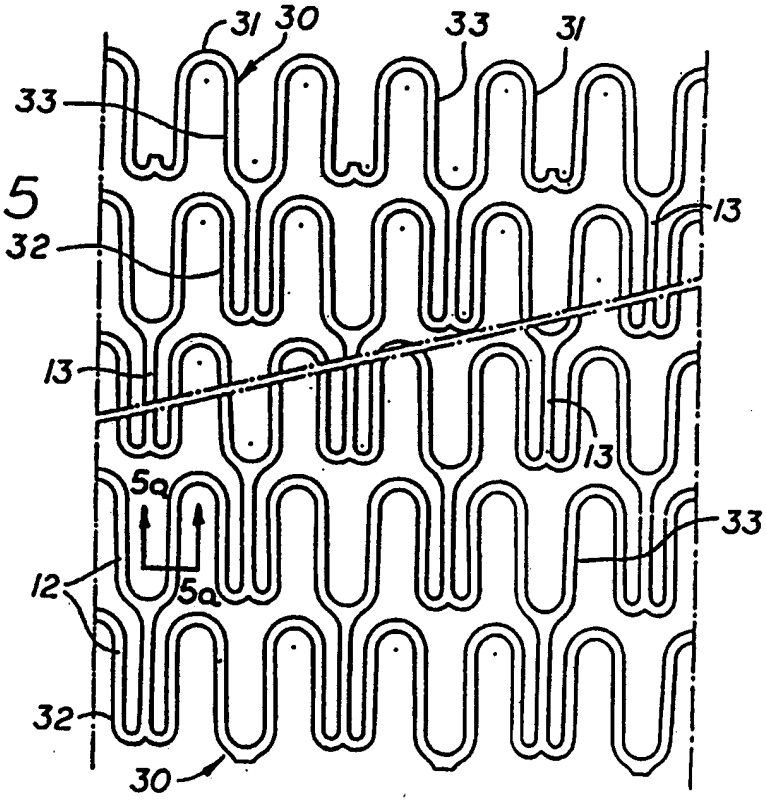


FIG. 5a

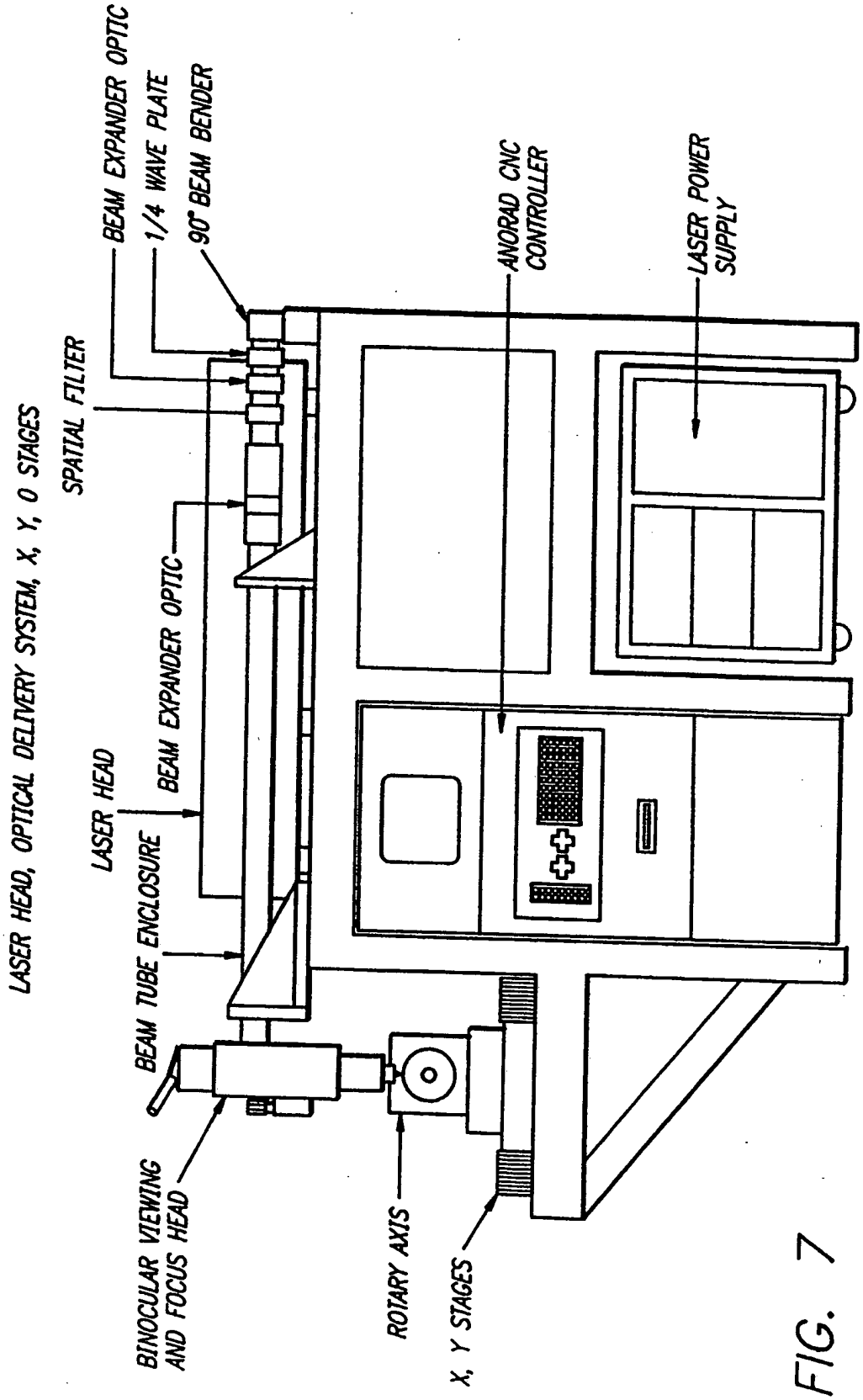
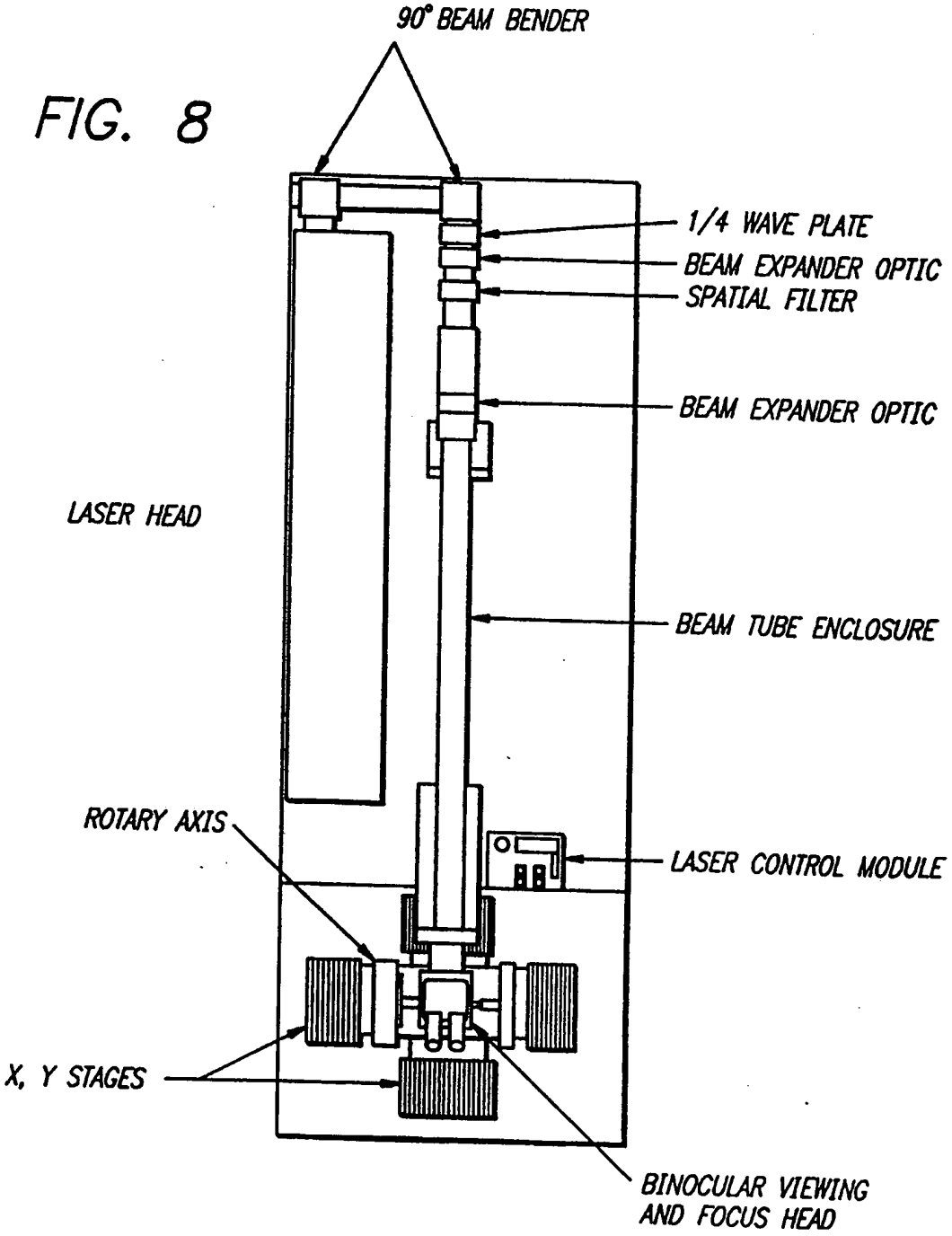

LASER HEAD, OPTICAL DELIVERY SYSTEM, X, Y, O STAGES
BEAM EXPANDER OPTIC
1/4 WAVE PLATE
90° BEAM BENDER
SPATIAL FILTER
BEAM EXPANDER OPTIC
LASER HEAD
BEAM TUBE ENCLOSURE
BINOCULAR VIEWING AND FOCUS HEAD
ROTARY AXIS
X, Y STAGES
ANORAD CNC CONTROLLER
LASER POWER SUPPLY

FIG. 7

LASER HEAD, OPTICAL DELIVERY SYSTEM, X, Y, O STAGES

FIG. 8



COAXIAL GAS JET - ROTARY COLLECT AND TUBE SUPPORT - TUBE BEAM BLOCK

FIG. 9

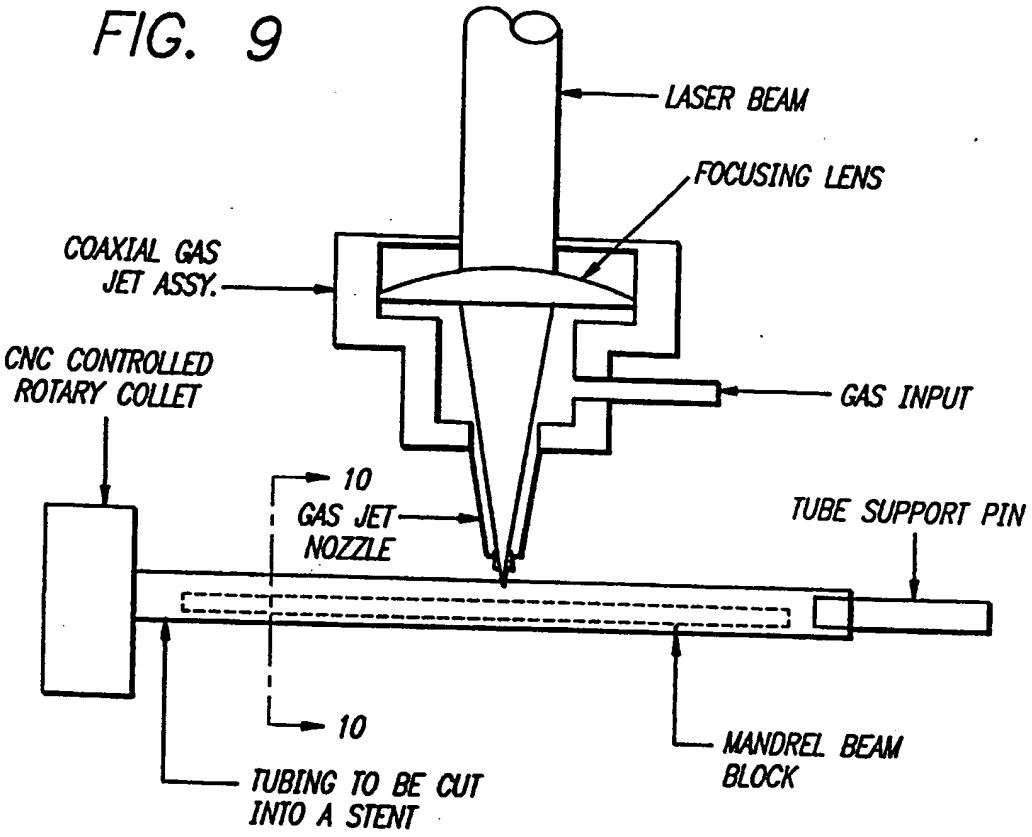
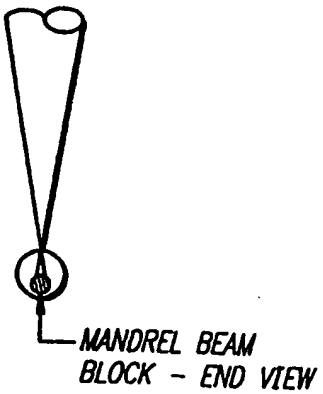
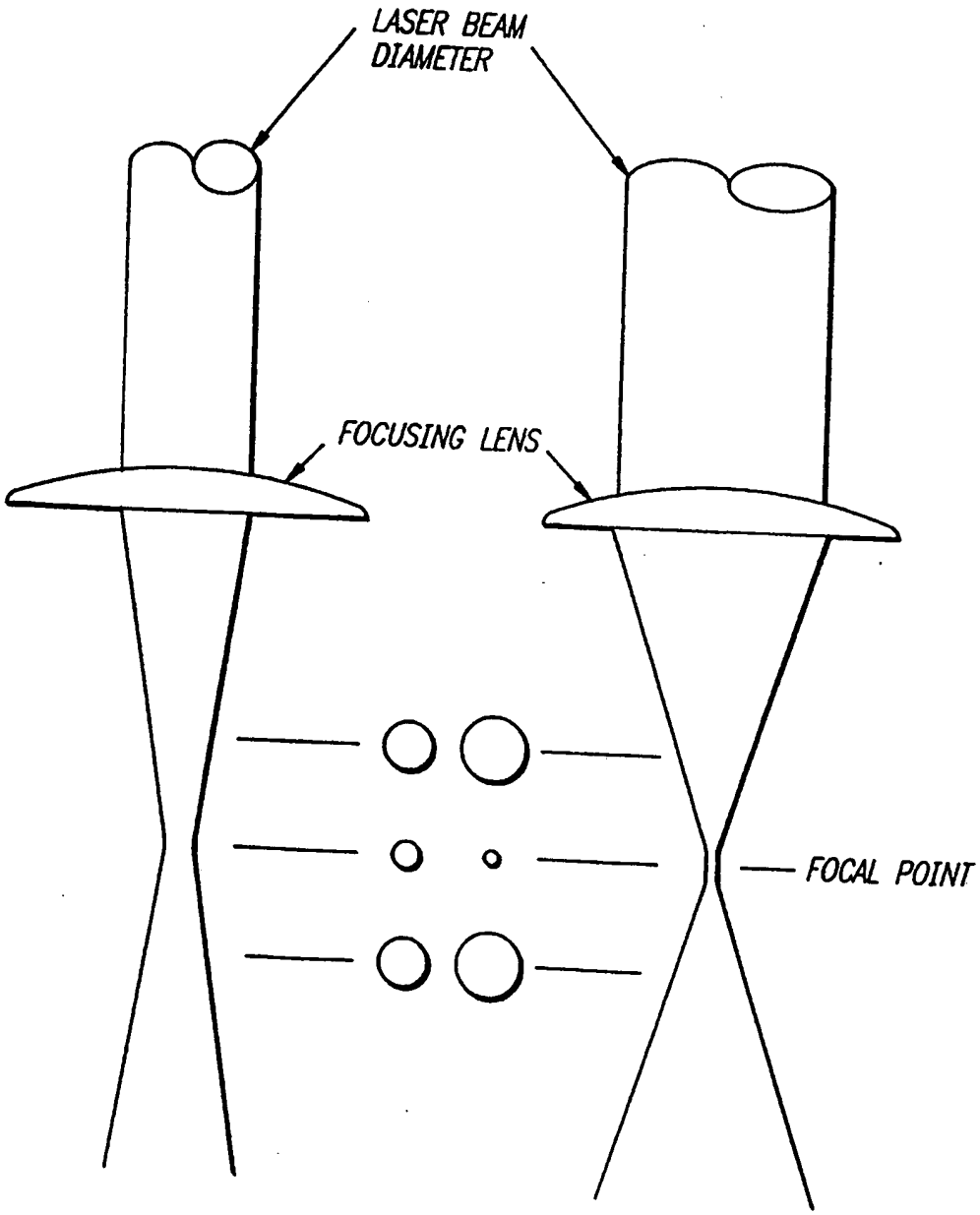


FIG. 10



BEAM DIAMETER VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 11



FOCAL LENGTH VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 12